REMARKS

In the ***final*** Office Action mailed November 23, 2009 the Office noted that claims 11 and 14-20 were pending and rejected claims 11 and 14-17, 19 and 20. In this amendment claim 11 has been amended, claim 15 has been canceled, and, thus, in view of the foregoing claims 11, 14, 17, 19 and 20 remain pending for reconsideration which is requested. No new matter has been added. The Office's rejections are traversed below.

CLAIM OBJECTION

Claims 11 and 15 stand objected to for informalities. In particular, the Office asserts that the claims contain repeater terms or are improperly dependent. The Applicants have amended the claims to overcome the objections.

Withdrawal of the objections is respectfully requested.

REJECTIONS under 35 U.S.C. § 103

Claims 11, 14, 15, 17, 19 and 20 stand rejected under 35 U.S.C. § 103(a) as being obvious over Salzman, U.S. Patent No. 5,423,320 in view of Fiddian-Greene, U.S. Patent No. 6,238,339. The Applicants respectfully disagree and traverse the rejection with an argument.

On page 4 of the Office Action, the Office asserts that Salzman discloses "wherein the distal end (22) of the second tube (2) is in ***direct*** communicating connection with the first tube

(1)," (emphasis added) as in amended claim 11. Support for the amendment may be found, for example, in Fig. 1, element 22. The Applicants submit that no new matter is believed to have been added by the amendment of claim 11. The Applicants submit that the amended claim adds no further search burden and the amendment should be entered as of right and considered.

Salzman col. 5, lines 6-8 states "… region 18 is spanned by a gas permeable membrane 20, to establish a closed gas sensing region coextensive with region 18. A first infrared (IR) light transmissive …."

Salzman col. 5, lines 6-8 states

> In the illustrated embodiment of FIG. 4, the membrane 20 is only on one side of the catheter, but in other embodiments the catheter may include multiple membranes in different circumferential locations. In the latter form, even if the distal tip is pressed against the gut wall, only one membrane would be blocked, while at least one other membrane would permit gas permeation into region 18.

It is just clear, that Salzman teaches the use of one or more gas sensing regions.

Salzman defines in claim 5 "one or more gas sensors affixed to said catheter near said distal end, wherein at least one of said gas sensors includes an open-faced ***chamber*** defined near the distal end of said catheter, and a gas permeable membrane spanning said open-faced ***chamber*** to define a closed gas-filled ***gas sensing region*** therein." (Emphasis added)

Whereas, claim 13 of Salzman recites "an open-faced ***chamber*** near said distal end and a gas permeable membrane

spanning said ***chamber*** to define a gas-filled ***gas sensing region***." (Emphasis added)

Thus, the Salzman catheter should be introduced into the patient's gastrointestinal tract. After a certain time due to transfer phenomenon through the gas permeable membrane spanning said open-faced chamber the C02 concentrations of the medium in the chamber and that of the gastrointestinal tract comes to an equilibrium. The time necessary to achieve a near equilibrium depends on the size of the membrane related to the volume of the chamber is low. This ratio of the Salzman catheter is quite low.

The presence of Salman's chamber has the consequence that distal ends of the tubes are not in mutual communicating connection with each other but with the chamber. The lumens of the tubes do not form a continuous flow path, therefore any medium introduced in one tube will mix with the contents of the chamber before discharging through the other one. Thereby the equilibrium of C02 contents gets destroyed and measured values will differ from the real ones.

Further, Fiddian-Green discusses the use of a sampling chamber (balloon) having a substantial volume related to the surface of the chamber. The tubing communicating with the sampling chamber is not made of a gas-permeable material. The balloon representing the sampling chamber must be inflated, kept under pressure for an extended time than the medium can be discharged for analysis. This is a complicated operation

requiring expensive equipment.

This prior art catheter does not have two parallel tubes made of a gas-permeable material. Only the wall of the sampling chamber is made of such material.

Unlike the cited prior art, the claimed device does not have any chamber, to the contrary, avoids any widening of the cross-section of the lumens of the tubes that might establish any dead space performing slower transport of C02 than other parts of the device to be inserted into the gastrointestinal tract of the patient. Claim 11 defines that distal ends of the tubes are in mutual communicating connection (i.e. are not in communicating connection with a chamber, balloon or any part different from the corresponding other tube). There is not any chamber or any other kind of dead space in the claimed tonometric device.

The claimed device has no gas sensing regions but the whole surface of the device is permeable to gases. One might say, that such an extensive active surface performs C02 transfer not only at the tip of the device, but along a relatively long section of the gastrointestinal tract and thereby the results of the measurement cannot be related to a definite part of the body. This circumstance, however, does not have any negative influence on the measurements.

The device claimed has an active surface/volume ratio exceeding by far that of prior art devices. This is due to the limitation that both tubes are made of a gas permeable material.

The distal end of the second tube is in communicating connection with the first tube. The omission of any chamber or similar widening of the lumen provides essential advantages: no dead space is present in the device, the whole volume of gaseous or liquid fluid inside the device is generally equally capable of performing C02 transfer with the gastrointestinal tract, respectively. As a consequence, the saturation rate of the fluid will be substantially uniform and rapid along the whole length of the lumens of the tubes of the device. The lumens of the communicatively connected tubes form a continuous flow path minimizing mixing effects, if any. The claimed device is gracile, does not cause serious discomfort and allows monitoring even premature neonates for longer time, as necessary.

For at least the reasons discussed above, Salztman and Fiddian-Greene, taken separately or in combination, fail to render obvious the features of claim 11 and the claims dependent therefrom.

Additionally, practical experience has proved that the claimed device delivers not only more accurate measurement results than others but the measurements are far quicker.

Though the device claimed is used presently in selected clinics only, sufficient practical experince have been gathered. All experiences support the outstanding advantages of the claimed solution over prior art devices. The claimed device is second to none in the ease of use, low cost measurement quickness,

smartness, etc…, particularly in case of neonates (even if premature).

The dimensions defined in the claims cover structural aspects rendering the device well usable for different patients. The device should be inflexible enough to be inserted into the gastrointestinal tract, but flexible enough not to cause excessive irritation. The dimensions may be cane lied from the independent claim.

The experiences with the claimed device have been reported by articles of prestigious periodicals. The following two articles have been mentioned on the internet at the site PubMed (U.S. National Library of Medicine, National Institutes of Health)

The corresponding articles are as follows:

1. Journal: Pediatric anesthesia

Title: Intraoperative gastric tonometric examinations in children and infants with a new probe, combined with measurement of the endtidal PC02.

Authors: Kiraly A, Boda D, Talosi G, Boda K.

Derartment of Anesthesiology, Medical Faculty, University of Szeged, Szeged, Hungary,

PubMed:

http://www.ncbi.nlm.nih.gov/pubmed/18312518

2. Journal: Medical science monitor: international medical journal of experimental and clinical research

Title: Applicability of a new gastric tonometric probe in infants requiring intensive care.

Authors: Talosi G, Boda D

Department of Pediatrics, Albert Szent-Gyorgyi Medical and Pharmaceutical Center,

Univetsity of Szeged, Szeged, Hungary.

PubMed:

http://www.ncbi.nlm.nih.gov/pubmed/18758429

A third article is accepted for publication by the periodical Journal of Critical Care. The article is already referred to in PubMed.

3. Journal: Journal of Critical Care

Title: Practical experiences and in vitro and in vivo validation studies with a new gastric tonometric probe in human adult patients.

Authors: Palagyi P, Vimlati L, Boda K, Talosi G, Boda D.

PubMed:

http://www.ncbi.nlm.nih.gov/pubmed/19217848?itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum&ordinalpos=8.

Withdrawal of the rejections is respectfully requested.

SUMMARY

It is submitted that the claims satisfy the

requirements of 35 U.S.C. § 103. It is also submitted that claims 11, 14, 17, 19 and 20 continue to be allowable. It is further submitted that the claims are not taught, disclosed or suggested by the prior art. The claims are therefore in a condition suitable for allowance. An early Notice of Allowance is requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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